Complete Summary

GUIDELINE TITLE

British guideline on the management of asthma. A clinical national guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN), British Thoracic Society. British guideline on the management of asthma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2005 Nov. 94 p. [666 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Scottish Intercollegiate Guidelines Network (SIGN), British Thoracic Society. British guideline on the management of asthma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN), British Thoracic Society; 2004 Apr. 91 p. (SIGN publication; no. 63). [568 references]

Scottish Intercollegiate Guidelines Network (SIGN). British guideline on the management of asthma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Jun 2. 26 p. [44 references]

Any amendments to the guideline will be noted on the <u>Scottish Intercollegiate Guidelines Network (SIGN) Web site</u>.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On November 18, 2005, the U.S. Food and Drug Administration (FDA) notified manufacturers of Advair Diskus, Foradil Aerolizer, and Serevent Diskus to update their existing product labels with new warnings and a Medication Guide for patients to alert health care professionals and patients that these medicines may increase the chance of severe asthma episodes, and death when those episodes occur. All of these products contain long-acting beta2-adrenergic agonists (LABA). Even though LABAs decrease the frequency of asthma episodes, these medicines may make asthma episodes more severe when they occur. A Medication Guide

with information about these risks will be given to patients when a prescription for a LABA is filled or refilled. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

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SCOPE

DISEASE/CONDITION(S)

Asthma

GUIDELINE CATEGORY

Diagnosis

Evaluation

Management

Prevention

Treatment

CLINICAL SPECIALTY

Allergy and Immunology

Critical Care

Emergency Medicine

Family Practice

Internal Medicine

Obstetrics and Gynecology

Pediatrics

Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses

Nurses

Pharmacists

Physician Assistants

Physicians

GUI DELI NE OBJECTI VE(S)

To provide comprehensive recommendations on asthma management for patients of all ages in both primary and secondary care that will be of use to all health professionals involved in the care of people with asthma

TARGET POPULATION

Children, adolescents, and adults with asthma

INTERVENTIONS AND PRACTICES CONSIDERED

Primary Prophylaxis

- 1. Encouragement of mothers to breastfeed their infants
- 2. Encouragement of parents and parents-to-be to stop smoking

Diagnosis/Evaluation

- 1. Detailed medical history and physical examination
- 2. Measurement of peak expiratory flow (PEF)
- 3. Measurement of forced expiratory volume in one second (FEV₁)
- 4. Chest x-ray
- 5. Allergy testing

Management/Treatment

Non-pharmacological Management

- 1. House dust mite control measures
- 2. Family therapy (i.e., in difficult childhood asthma, as an adjunct to pharmacological therapy)
- 3. Weight reduction in obese patients
- 4. Treatment of gastro-oesophageal reflux if present

Pharmacological Management

Note: The type of pharmacological management varies by age group. See the "Major Recommendations" field and the original guideline document for specific information on which interventions are recommended for each age group.

Step 1: Mild Intermittent Asthma

- 1. Short acting inhaled beta₂ agonists
- 2. Inhaled ipratropium bromide
- 3. Beta₂ agonists tablets or syrup
- 4. Theophyllines

Step 2: Introduction of Regular Preventer Therapy

1. Inhaled steroids

- 2. Chromones
- 3. Leukotriene receptor antagonists
- 4. Theophyllines

Step 3: Add-on Therapy

- 1. Inhaled long acting beta₂ agonists (LABAs)
- 2. Oral steroids, such as prednisolone
- 3. Leukotriene receptor antagonists
- 4. Theophyllines
- 5. Slow release beta₂ agonist tablets

Step 4: Addition of Fourth Drug (in Cases of Poor Control on Moderate Dose of Inhaled Steroid + Add-on Therapy)

- 1. Increased doses of inhaled steroid
- 2. Leukotriene receptor antagonists
- 3. Theophyllines
- 4. Slow release beta₂ agonist tablets

Step 5: Continuous or Frequent Use of Oral Steroids

- 1. Inhaled steroids
- 2. Trial of LABAs, leukotriene receptor antagonists, or theophyllines
- 3. Immunosuppressants, such as methotrexate, cyclosporin, oral gold

Other Interventions Considered

- 1. Intranasal steroids for the treatment of rhinitis
- 2. Itraconazole for the treatment of allergic bronchopulmonary aspergillosis (ABPA)

Inhaler Devices

- 1. Pressurized metered-dose inhaler (pMDI) with or without spacer
- 2. Dry powder inhaler (DPI)
- 3. Nebuliser

Acute Asthma

Note: Management and treatment of acute asthma varies by age group. See "Major Recommendations" and the original guideline document for specific information on which interventions are recommended for each age segment.

- 1. Clinical assessment
- 2. Referral to hospital, when necessary
- 3. High flow oxygen
- 4. Nebulised beta₂ agonist bronchodilator driven by oxygen or large volume spacers or nebulisers
- 5. Intravenous beta₂ agonist
- 6. Continuous nebulisation

- 7. Steroid treatment, such as prednisolone
- 8. Nebulised ipratropium bromide
- 9. Intravenous magnesium sulphate
- 10. Intravenous salbutamol
- 11. Intravenous aminophylline
- 12. Follow-up

Education/Counseling

- 1. Training on inhaler technique
- 2. Pre-pregnancy counseling
- 3. Self-management education, including pre-discharge education and action plans

MAJOR OUTCOMES CONSIDERED

- Patient symptoms
- Results of diagnostic tests
- Morbidity and mortality
- Side effects of treatments

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The electronic searches extended to 1995, although some sections required literature searches to go as far back as 1966. The Pharmacology section utilised the North of England Asthma Guideline to address any key questions on adult pharmacological management covered by that document. The North of England Guideline literature search covered a period from 1984 to December 1997, and the Scottish Intercollegiate Guidelines Network (SIGN) augmented this with a search from 1997 onwards. The April 2004 version of the guideline is based on a literature search dating up to and including March 2003, and the September 2005 changes are based on a search up to and including March 2004 with additional searches for section 4 carried out in August 2004. The changes to section 8 were developed using a comprehensive evidence based guideline on occupational asthma published by the British Occupational Health Research Foundation, developed using methodology similar to SIGN's. The British Thoracic Society (BTS)/SIGN occupational asthma sub-group were represented in this process and have selected those recommendations relevant to less specialized asthma management for inclusion here.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

- 1++ High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
- 1+ Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
- 1- Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
- 2++ High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
- 2+ Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
- 2- Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
- 3 Nonanalytic studies (e.g. case reports, case series)
- 4 Expert opinion

METHODS USED TO ANALYZE THE EVI DENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. SIGN has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will

affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

This guideline was jointly produced by SIGN and the British Thoracic Society (BTS), using SIGN methodology, adapted for United Kingdom-wide development. The National Asthma Campaign, the Royal College of Physicians of London, the Royal College of Paediatrics and Child Health, General Practice Airways group, and the British Association of Accident and Emergency Medicine also collaborated in the development of this guideline.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the <u>SIGN Web site</u>.

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the group are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are <u>not</u> an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS.

The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

Grade A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

Grade B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

Grade C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rate as 2++

Grade D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A national open meeting is the main consultative phase of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development, at which the guideline development group presents their draft recommendations for the first time. The national open meeting for this guideline was held in October 2001 and was attended by 346 representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the SIGN and British Thoracic Society (BTS) Web sites for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

The guideline was reviewed in draft form by a panel of independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline.

The guideline was then reviewed by an Editorial Group comprising relevant specialty representatives on SIGN Council, to ensure that the peer reviewers' comments had been addressed adequately and that any risk of bias in the guideline development process as a whole had been minimised.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): In November 2005, the Scottish Intercollegiate Guidelines Network (SIGN) released an update of their 2004 asthma guideline. The changes made in the 2005 update have been incorporated into the summary below. In addition, a document identifying changes made in the November 2005 update of this guideline is available on the SIGN Web site.

Note from SIGN and NGC: In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.

The grades of recommendations (A-D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Diagnosis and Natural History

Diagnosis of Asthma in Children

- D Base the diagnosis of asthma in children on:
- The presence of key features and careful consideration of alternative diagnoses (see table 2 in the original guideline document)
- Assessment of the response to trials of treatment, and ongoing assessment
- Repeated reassessment of the child, questioning the diagnosis if management is ineffective

Non-pharmacological Management

Primary Prophylaxis

- A Breastfeeding should be encouraged and its benefits include a protective effect in relation to early life wheezing.
- B Parents and parents-to-be who smoke should be advised of the many adverse effects of smoking on their children, including increased wheezing in infancy, and be offered appropriate support to stop smoking.

Environmental Factors

B - Parents who smoke should be advised about the dangers for themselves and their children and offered appropriate support to stop smoking.

Dietary Manipulation

C - Weight reduction is recommended in obese patients with asthma to improve asthma control.

Gastro-oesophageal Reflux in Asthma

B - Gastro-oesophageal reflux should be treated if present but this will generally have no impact on asthma control.

Pharmacological Management

In this and the following section ("Inhaler Devices"), each recommendation has been graded for adults, children 5-12 years, and children under 5 years. See

Figures 4, 5, and 6 in the original guideline document for a summary of stepwise management in each of the age segments.

Step 1: Mild Intermittent Asthma

Adults: A; Children aged 5 to 12 years: B; Children under 5 years: D - Prescribe an inhaled short acting beta₂ agonist as short term reliever therapy for all patients with symptomatic asthma.

Adults: B; Children aged 5 to 12 years: D; Children under 5 years: D - Patients with high usage of inhaled short acting beta $_2$ agonists should have their asthma management reviewed.

Step 2: Introduction of Regular Preventer Therapy

Adults: A; Children aged 5 to 12 years: A; Children under 5 years: A - Inhaled steroids are the recommended preventer drug for adults and children for achieving overall treatment goals.

Adults: B; Children aged 5 to 12 years: C; Children under 5 years: Good Practice Point - Inhaled steroids should be considered for patients with any of the following: exacerbations of asthma in the last two years; using inhaled beta agonists three times a week or more; symptomatic three times a week or more, or waking one night a week.

Adults: A; Children aged 5 to 12 years: D; Children under 5 years: D - Give inhaled steroids initially twice daily.

Adults: A; Children aged 5 to 12 years: D; Children under 5 years: D - Once a day inhaled steroids at the same total daily dose can be considered (within product licence) if good control is established.

Step 3: Add-on Therapy

Adults: A; Children aged 5 to 12 years: B; Children under 5 years: Good Practice Point - Carry out a trial of other treatments before increasing the inhaled steroid dose above 800 micrograms/day in adults and 400 micrograms/day in children.

Adults: A; Children aged 5 to 12 years: B; Children under 5 years: Recommendation does not apply to this age group. - The first choice as add-on therapy to inhaled steroids in adults and children (5-12 years) is an inhaled long acting beta₂ agonist.

Adults: D; Children aged 5 to 12 years: D; Children under 5 years: Recommendation does not apply to this age group. - If asthma control remains suboptimal after the addition of an inhaled long acting beta₂ agonist, then the dose of inhaled steroids should be increased to 800 micrograms/day in adults or 400 micrograms/day in children (5-12 years).

Step 4: Poor Control on Moderate Dose of Inhaled Steroid + Add-on Therapy: Addition of Fourth Drug

Adults: D; Children aged 5 to 12 years: D; Children under 5 years: Recommendation does not apply to this age group. - If control remains inadequate on 800 micrograms daily (adults) and 400 micrograms daily (children) of an inhaled steroid plus a long acting beta₂ agonist, consider the following interventions:

- Increasing inhaled steroids to 2,000 micrograms/day (adults) or 800 micrograms/day (children 5-12 years)
- Leukotriene receptor antagonists
- Theophyllines
- Slow release beta₂ agonist tablets, though caution needs to be used in patients on long acting beta₂ agonists.

Step 5: Continuous or Frequent Use of Oral Steroids

Adults: A; Children aged 5 to 12 years: D; Children under 5 years: Recommendation does not apply to this age group. - In adults the recommended method of eliminating or reducing the dose of steroid tablets is inhaled steroids, at doses of up to 2,000 micrograms/day if required. In children aged 5 to 12, consider very carefully before going above a dose of 1,000 micrograms/day.

Adults: D; Children aged 5 to 12 years: D; Children under 5 years: D - There is a role for a trial of treatment with long acting beta₂ agonists, leukotriene receptor antagonists, and theophyllines for about six weeks. They should be stopped if no improvement in steroid dose, symptoms, or lung function is detected.

Specific Management Problems

If exercise is a specific problem in patients taking inhaled steroids who are otherwise well controlled, consider the following therapies:

Adults: A; Children aged 5 to 12 years: C; Children under 5 years: Recommendation does not apply to this age group. - Leukotriene receptor antagonists

Adults: A; Children aged 5 to 12 years: A; Children under 5 years: Recommendation does not apply to this age group. - Long acting beta₂ agonists

Adults: C; Children aged 5 to 12 years: C; Children under 5 years: Recommendation does not apply to this age group. - Chromones

Adults: A; Children aged 5 to 12 years: A; Children under 5 years: Recommendation does not apply to this age group. - Oral beta₂ agonists

Adults: C; Children aged 5 to 12 years: C; Children under 5 years: Recommendation does not apply to this age group. - Theophyllines

Adults: A; Children aged 5 to 12 years: A; Children under 5 years: Good practice point - Immediately before exercise, inhaled short acting beta₂ agonists are the drug of choice

Adults: C; Children aged 5 to 12 years: Recommendation does not apply to this age group; Children under 5 years: Recommendation does not apply to this age group. - In adult patients with allergic bronchopulmonary aspergillosis (ABPA), a four month trial of itraconazole should be considered.

Inhaler Devices

Technique and Training

Adults: B; Children aged 5 to 12 years: Good practice point; Children under 5 years: Good practice point. - Prescribe inhalers only after patients have received training in the use of the device and have demonstrated satisfactory technique.

Beta₂ Agonist Delivery

Adults: A; Children aged 5 to 12 years: A; Children under 5 years: B. - Children and adults with mild and moderate exacerbations of asthma should be treated by pressurized metered dose inhaler (pMDI) + spacer with doses titrated according to clinical response.

Adults: Recommendation does not apply to this age group; Children aged 5 to 12 years: A; Children under 5 years: Recommendation does not apply to this age group. - In children aged 5 to 12, pMDI + spacer is as effective as any other hand held inhaler.

Adults: A; Children aged 5 to 12 years: Recommendation does not apply to this age group; Children under 5 years: Recommendation does not apply to this age group. - In adults, pMDI <u>+</u> spacer is as effective as any other hand held inhaler, but patients may prefer some types of dry powder inhaler (DPI).

Inhaled Steroids for Stable Asthma

Adults: Recommendation does not apply to this age group; Children aged 5 to 12 years: A; Children under 5 years: Recommendation does not apply to this age group. - In children aged 5 to 12 years, pMDI + spacer is as effective as any DPI.

Adults: A; Children aged 5 to 12 years: Recommendation does not apply to this age group; Children under 5 years: Recommendation does not apply to this age group. - In adults, a pMDI \pm spacer is as effective as any DPI.

Chlorofluorocarbon (CFC) Propellant pMDI versus Hydrofluoroalkane (HFA) Propellant pMDI

Adults: A; Children aged 5 to 12 years: Recommendation does not apply to this age group; Children under 5 years: Recommendation does not apply to

this age group. - Salbutamol HFA can be substituted for salbutamol CFC at 1:1 dosing.

Adults: A; Children aged 5 to 12 years: Recommendation does not apply to this age group; Children under 5 years: Recommendation does not apply to this age group. - HFA beclomethasone (BDP) pMDI (Qvar) may be substituted for CFC BDP pMDI at 1:2 dosing. This ratio does not apply to reformulated HFA BDP pMDIs.

Adults: A; Children aged 5 to 12 years: Recommendation does not apply to this age group; Children under 5 years: Recommendation does not apply to this age group. - Fluticasone HFA can be substituted for fluticasone CFC at 1:1 dosing.

Management of Acute Asthma

Lessons from Studies of Asthma Deaths and Near Fatal Asthma

B - Health care professionals must be aware that patients with severe asthma and one or more adverse psychosocial factors are at risk of death.

Acute Asthma in Adults

- D Refer to hospital any patients with features of acute severe or life threatening asthma.
- B Admit patients with any feature of a life threatening or near fatal attack. (Wareham et al., 1993; Mohan et al., 1996; Bucknall et al., 1999; Burr et al., 1999; British Thoracic Association Research Committee, 1984; Campbell et al., 1997; Innes et al., 1998)
- B Admit patients with any feature of a severe attack persisting after initial treatment. (Wareham et al., 1993; Mohan et al., 1996; Bucknall et al., 1999; Burr et al., 1999; British Thoracic Association Research Committee, 1984; Campbell et al., 1997; Innes et al., 1998)
- C Patients whose peak flow is greater than 75% best or predicted one hour after initial treatment may be discharged from accident and emergency (A&E), unless they meet any of the following criteria, when admission may be appropriate:
- Still have significant symptoms
- Concerns about compliance
- Living alone/socially isolated
- Psychological problems
- Physical disability or learning difficulties
- Previous near fatal or brittle asthma
- Exacerbation despite adequate dose steroid tablets prepresentation
- Presentation at night
- Pregnancy

Treatment of Acute Asthma in Adults

C - Give high flow oxygen to all patients with acute severe asthma.

A -

- In hospital, ambulance and primary care, nebulised beta₂ agonist bronchodilators should be driven by oxygen
- Outside hospital, high dose beta₂ agonist bronchodilators may be delivered via large volume spacers or nebulisers.
- C Whilst supplemental oxygen is recommended, its absence should not prevent nebulised therapy being given if indicated.
- A Use high dose inhaled beta₂ agonists as first line agents in acute asthma and administer as early as possible. Intravenous beta₂ agonists should be reserved for those patients in whom inhaled therapy cannot be used reliably.
- A In severe asthma (peak expiratory flow [PEF] or forced expiratory volume in one second [FEV $_1$] <50% best or predicted) and asthma that is poorly responsive to an initial bolus dose of beta $_2$ agonist, consider continuous nebulisation, using an appropriate nebuliser system.
- A Give steroid tablets in adequate doses in all cases of acute asthma.
- A Nebulised ipratropium bromide (0.5 mg 4-6 hourly) should be added to beta₂ agonist treatment for patients with acute severe or life threatening asthma or those with a poor initial response to beta₂ agonist therapy.
- A Consider giving a single dose of intravenous (IV) magnesium sulphate for patients with:
- Acute severe asthma who have not had a good initial response to inhaled bronchodilator therapy
- Life threatening or near fatal asthma
- B Routine prescription of antibiotics is not indicated for acute asthma.
- C All patients transferred to intensive care units should be accompanied by a doctor suitably equipped and skilled to intubate if necessary.

Acute Asthma in Children Aged Over 2 Years

- B Consider intensive inpatient treatment for children with $SpO_2 < 92\%$ on air after initial bronchodilator treatment.
- D The use of structured care protocols detailing bronchodilator usage, clinical assessment, and specific criteria for safe discharge is recommended.
- A Inhaled beta₂ agonists are the first line treatment for acute asthma. (Schuh et al., 1989; Schuh et al., 1990; Robertson et al., 1985; Schuh et al., 1999)

- A pMDI + spacer are the preferred option in mild to moderate asthma.
- B Individualise drug dosing according to severity and adjust according to the patient's response.
- B The early addition of a bolus dose of intravenous salbutamol (15 micrograms/kg) can be an effective adjunct to treatment in severe cases.
- A Give prednisolone early in the treatment of acute asthma attacks.
- A If symptoms are refractory to initial beta₂ agonist treatment, add ipratropium bromide (250 micrograms/dose mixed with the nebulised beta₂ agonist solution).
- A Aminophylline is not recommended in children with mild to moderate acute asthma.
- C Consider aminophylline in a High Dependency Unit or pediatric intensive care unit (PICU) setting for children with severe or life threatening bronchospasm unresponsive to maximal doses of bronchodilators and steroid tablets.

Treatment of Acute Asthma in Children Aged <2 Years

- B Oral beta₂ agonists are not recommended for acute asthma in infants.
- A For mild to moderate acute asthma, a pMDI + spacer is the optimal drug delivery device.
- B Consider steroid tablets in infants early in the management of moderate to severe episodes of acute asthma in the hospital setting.
- B Consider inhaled ipratropium bromide in combination with an inhaled beta₂ agonist for more severe symptoms.

Asthma in Pregnancy

Natural History

- D Offer prepregnancy counselling to women with asthma regarding the importance and safety of continuing their asthma medications during pregnancy to ensure good asthma control.
- C Monitor pregnant women with asthma closely so that any change in course can be matched with an appropriate change in treatment.

Management of Acute Asthma in Pregnancy

- C Give drug therapy for acute asthma as for the nonpregnant patient.
- D Deliver oxygen immediately to maintain saturation above 95%.

D - Acute severe asthma in pregnancy is an emergency and should be treated vigorously in hospital.

Drug Therapy in Pregnancy

- C Use beta₂ agonists as normal during pregnancy.
- C Use inhaled steroids as normal during pregnancy.
- C Use oral and intravenous theophyllines as normal during pregnancy.
- D Check blood levels of theophylline in acute severe asthma and in those critically dependent on therapeutic theophylline levels.
- C Use steroid tablets as normal when indicated during pregnancy for severe asthma. Steroid tablets should never be withheld because of pregnancy.
- D Do not commence leukotriene antagonists during pregnancy. They may be continued in women who have demonstrated significant improvement in asthma control with these agents prior to pregnancy not achievable with other medications.
- C Use chromones as normal during pregnancy.

Management During Labour

- C If anaesthesia is required, regional blockade is preferable to general anaesthesia in women with asthma.
- D Use prostaglandin F2-alpha with extreme caution in women with asthma because of the risk of inducing bronchoconstriction.

Drug Therapy in Breastfeeding Mothers

- C Encourage women with asthma to breastfeed.
- C Use asthma medications as normal during lactation, in line with manufacturer's recommendations.

Occupational Asthma

Incidence

B - In patients with adult onset asthma, or reappearance of childhood asthma, clinicians should be suspicious that there may be an occupational cause.

Diagnosis

D - In suspected work-related asthma, the diagnosis of asthma should be confirmed using standard objective criteria.

- D Objective diagnosis of occupational asthma should be made using serial peak flow measurements, with at least four readings per day.
- D A negative specific bronchial challenge in a worker with otherwise good evidence of occupational asthma is not sufficient to exclude the diagnosis.

Management of Occupational Asthma

D - Relocation away from exposure should occur as soon as diagnosis is confirmed, and ideally within 12 months of the first work-related symptoms of asthma.

Organisation and Delivery of Care

Routine Care

- B All people with asthma should have access to primary care delivered by clinicians with appropriate training in asthma management.
- B In primary care, people with asthma should be reviewed regularly by a nurse or doctor with appropriate training in asthma management.
- C General practices should maintain a list of people with asthma.
- C Clinical review should be structured and utilise a standard recording system.
- B Feedback of information to clinicians should link individual patients with recommendations from guidelines.
- D Health professionals who provide asthma care should have heightened awareness of the complex needs of ethnic minorities, socially disadvantaged groups, and those with communication difficulties.

Acute Exacerbations

- C Manage hospital inpatients in specialist rather than general units, where available.
- B Clinicians in primary and secondary care should treat asthma according to recommended guidelines.
- B Discharge from hospital or the emergency department should be a planned, supervised event.
- B All people attending hospital with acute exacerbations of asthma should be reviewed by a clinician with expertise in asthma management, preferably within 30 days.

Patient Education and Self-management

Personalised Asthma Action Plans

A - Patients with asthma should be offered self-management education that should focus on individual needs, and be reinforced by a written action plan.

A - Prior to discharge, in-patients should receive individualised asthma action plans, given by clinicians with appropriate training in asthma management.

B - Introduce asthma action plans as part of a structured educational discussion.

<u>Definitions</u>:

Grades of Recommendation

The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

Grade A: At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or randomised controlled trial rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

Grade B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

Grade C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

Grade D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

Levels of Evidence

1++ - High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+ - Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

- 1- Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
- 2++ High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
- 2+ Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
- 2- Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
- 3 Nonanalytic studies (e.g. case reports, case series)
- 4 Expert opinion

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Management of acute severe asthma in adults in general practice
- Management of acute severe asthma in adults in Accident and Emergency (A&E)
- Management of acute severe asthma in adults in hospital
- Management of acute asthma in children in general practice (age 2-5 years)
- Management of acute asthma in children in general practice (age > 5 years)
- Management of acute asthma in children in A&E (age 2-5 years)
- Management of acute asthma in children in A&E (age > 5 years)
- Management of acute asthma in children in hospital (age 2-5 years)
- Management of acute asthma in children in hospital (age > 5 years)
- Management of acute asthma in infants aged <2 in hospital
- Work-related asthma and rhinitis: case finding and management in primary care
- Diagnosis of asthma in children
- Pharmacological management of asthma: add-on therapy
- Summary of stepwise management in adults
- Summary of stepwise management in children aged 5-12 years
- Summary of stepwise management in children less than 5 years

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Control of symptoms, including nocturnal symptoms and exercise-induced asthma
- Prevention of exacerbations
- Achievement of best possible pulmonary function with minimal side effects

POTENTIAL HARMS

There may be side effects associated with the use of certain asthma medications. Refer to the original guideline document for details.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Beta-blockers, including eye drops, are contraindicated in patients with asthma
- During labour, use prostaglandin F2-alpha with extreme caution in women with asthma because of the risk of inducing bronchoconstriction.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline is not intended to be construed or to serve as a standard of medical care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor, following discussion of the options with the patient, in light of the diagnostic and treatment choices available. However, it is advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Dissemination and Implementation

A number of initiatives are underway to support the implementation of the guideline. These include:

- Dissemination activities including mailings and the use of lay and medical media
- Distribution of profession- and locality-specific summaries
- Distribution of educational materials including "off-the-shelf" presentation packages, case histories suitable for discussion, and scenarios for problembased learning (available on CD-ROM and the Scottish Intercollegiate Guidelines Network [SIGN] and British Thoracic Society [BTS] Web sites; see the related "Companion Documents" field for further information)
- Distribution of summary wall charts for different health care settings
- Electronic links between the guideline and electronic support systems, e.g., GPASS and VAMP in primary care to enhance intraconsultation prompting
- Development and distribution of patient information materials (see the related "Patient Resources" field for further information).

Further details of these initiatives are available on the <u>SIGN Web site</u> and <u>BTS Web site</u>.

Outcomes and Audit

Evidence suggests that guidelines alone do not affect clinical practice. Feedback based on audit is useful, both as part of an implementation strategy and for longer term positive influence on practice. The recommendations listed below are intended to assist in auditing the recommendations contained in the guideline. The gradings relate to the benefit demonstrated for the intervention being audited. Audit datasets (including definitions) are listed in Annex 9 of the original guideline document.

The grades of recommendations (A-D) are defined at the end of the "Description of Implementation Strategy" field.

Primary Care and Hospital Clinics

- C Use a structured record for asthma patients, including a system for recording inhaler technique, morbidity, peak expiratory flow (PEF) levels, current treatment, and asthma action plans.
- B Practices should offer nurse-run structured care for targeted patients with asthma.
- C Health professionals should be involved in clinical audit.
- A Self-regulation based continuing medical education (CME) courses on asthma management are recommended for doctors.

Identify groups of patients at risk:

- C Children with frequent consultations with respiratory infection
- A Children over 5 years with persistent symptoms of asthma
- C Patients with asthma and psychiatric disease or learning disability
- B Patients using large quantities of beta₂ agonists

- B Monitor the provision of asthma action plans, particularly to patients:
- With moderate or severe asthma, based on step 3 or above
- With regular symptoms
- Having frequent steroid courses or exacerbations
- Having emergency nebulisation or accident and emergency attendances/hospitalisations
- Seeing different doctors
- C Specialist review in adults with continuing symptoms is recommended to confirm or refute a diagnosis of asthma and to identify and manage the causes of persistent symptoms.

Monitor the proportion of patients with active disease or taking asthma treatment, including those:

- C Having no or few current symptoms
- A Able to use their prescribed inhalers effectively
- A Using inhaled steroids
- C With normal lung function (PEF or forced expiratory volume in one second [FEV₁] >80% predicted)
- C With actual/best PEF or FEV₁ >85%
- A With an asthma action plan (patients who should have an action plan include those on step 3 or above, plus any not on this level of treatment who have had an emergency nebulisation, a course of oral steroids, or accident and emergency attendance or hospital admission with asthma within the past 12 months).
- B Recommended tools for monitoring morbidity: Royal College of Physicians (RCP) three questions (see section 12 in the original guideline document) or tools which incorporate these (such as the Tayside stamp, Jones index, and Q score).

Outcomes for Management of Acute Asthma in Primary Care

Monitor the proportion of patients attending for an unscheduled appointment or seen urgently, including those receiving emergency nebulisation who:

- C Who have PEF measured
- A Are given steroid tablets
- C Are seen for review after an unscheduled visit, in order to confirm improvement (objectively, with PEF) and target them for teaching of selfmanagement skills

Accident and Emergency Care for Patients with Asthma

C - Structure asthma care to prompt the recording of key aspects of assessment and treatment (include historical data on previous attendances, corticosteroid, home nebuliser use, administration of steroid tablets, pulse, PEF, oxygen saturations, arterial blood gases).

- A Monitor access to an asthma specialist nurse for teaching of self-management skills (adults).
- B Monitor the rate of referral for specialist medical review.
- A Monitor the proportion of patients with acute asthma who are treated with steroid tablets within one hour of attendance, and the overall percentage.

Hospital Inpatients with Acute Asthma

- C Monitor the proportion of patients seen by a respiratory specialist.
- A Monitor the proportion of patients seen by an asthma specialist nurse.
- B Monitor the availability of outpatient programmes teaching self-management skills for those who have had a recent hospital admission.
- C Monitor the use of prompts (e.g., stamps, proformas, clinical pathways) to promote good quality of care and improve the collection of relevant process of care data.
- C Measure adherence to guideline recommendations using the BTS (adults) or British Paediatric Respiratory Society (BPRS) (children) audit tools (available at www.brit-thoracic.org.uk).

Outcomes of Care for Hospital Management of Acute Asthma

B - Monitor readmission rates (within two months), where readmissions can be linked between different institutions or are only likely to occur to the same institution.

Grades of Recommendation

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Grade A: At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or randomised controlled trial rated as 1++ and directly applicable to the target population; or

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Extrapolated evidence from studies rated as 1++ or 1+

Grade C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

Grade D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

IMPLEMENTATION TOOLS

Audit Criteria/Indicators Chart Documentation/Checklists/Forms Clinical Algorithm Quick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN), British Thoracic Society. British guideline on the management of asthma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2005 Nov. 94 p. [666 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Jan (revised 2005 Nov)

GUIDELINE DEVELOPER(S)

British Thoracic Society - Medical Specialty Society Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUI DELI NE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned, e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry; a non-personal interest involves payment which benefits any group, unit or department for which the individual is responsible, e.g., endowed fellowships or other pharmaceutical industry support. SIGN guideline group members should be able to act as independently of external commercial influences as possible, therefore, individuals who declare considerable

^{*} Executive group

personal interests may be asked to withdraw from the group. Details of the declarations of interest of any guideline development group member(s) are available from the SIGN executive.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Scottish Intercollegiate Guidelines Network (SIGN), British Thoracic Society. British guideline on the management of asthma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN), British Thoracic Society; 2004 Apr. 91 p. (SIGN publication; no. 63). [568 references]

Scottish Intercollegiate Guidelines Network (SIGN). British guideline on the management of asthma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Jun 2. 26 p. [44 references]

Any amendments to the guideline will be noted on the <u>Scottish Intercollegiate</u> <u>Guidelines Network (SIGN) Web site</u>.

GUIDELINE AVAILABILITY

Electronic copies of the original guideline: Available from the <u>Scottish</u> Intercollegiate Guidelines Network (SIGN) Web site.

Electronic copies of the addendum: Available from the SIGN Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: British guideline on the management of asthma. Edinburgh (UK): Scottish Intercollegiate Guidelines Network, 2004 May. 20 p. Available in Portable Document Format (PDF) from the <u>Scottish Intercollegiate</u> <u>Guidelines Network (SIGN) Web site</u>. Addendum to the April 2004 Guideline available from the <u>SIGN</u> Web site.
- SIGN 50: a guideline developers' handbook. Edinburgh (UK): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research and Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.
- A background paper on the legal implications of guidelines. Edinburgh (Scotland): Scotlish Intercollegiate Guidelines Network.
- A sample Personal action plan can be found in Annex 8 of the <u>original</u> <u>guideline document</u>.
- Audit criteria are available in Annex 9 of the <u>original guideline document</u>.

PATIENT RESOURCES

None available

NGC STATUS

This summary was prepared by ECRI on November 20, 2003. An addendum to this summary was prepared on September 8, 2004. The information was verified by the guideline developer on December 2, 2004. This NGC summary was updated by ECRI on December 5, 2005.

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